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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,417	11/04/2003	Alfred Binggeli	21477	5814

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HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/700,417

Applicant(s)

BINGGELI ET AL.

Examiner

Laura L. Stockton, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 51 and 54-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 16-20, 22-26, 29-35, 39-47, 50, 52 and 53 is/are rejected.
- 7) ☒ Claim(s) 13-15, 21, 27, 28, 36-38, 48 and 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/4/03 & 5/6/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-56 are pending in the application.

Election/Restrictions

Applicants' election with traverse of Group I, and the species of Example 47 (named below) in the reply filed on January 10, 2005 is acknowledged. The traversal is on the ground(s) that: (1) there is no serious burden to examine Groups I and II together because they are classified in the same class and subclass; (2) Group II is specifically directed to the manufacture of compounds of Group I and does not cover the manufacture of materially different products; (3) the methods of using found in Group III are directed to methods of treatment using the same products of Group I; and (4) the issues related to search and examination are the same or closely related for each group and therefore no serious burden would be imposed by examining all the Groups together.

All of Applicants' arguments have been considered but have not been found persuasive. Each of the groups outlined in the Restriction

Requirement of December 10, 2004 are directed toward a separate statutory class of invention. As stated in the Restriction Requirement on page 3, the instant claimed process can be used to make other materially different products since the process of instant claim 51 is the removal of a protecting group to obtain the final products. Additionally, as stated in the Restriction Requirement on page 3, the claimed method of using the products can be practiced with another materially different product. For example, there are plenty of drugs on the market that treat diseases such as diabetes, elevated blood pressure, inflammatory diseases, etc. Further, separate search considerations are involved for each of the outlined groups, not just class and subclass searches. Therefore, it would impose an undue burden on the Examiner and the Patent Office's resources if the instant application is examined in its entirety.

Example 47

a) [rac]-3-{4-[2-(2-tert-Butyl-5-methyl-oxazol-4-yl)-ethoxy]-2-methyl-phenyl}-2-ethoxy-propionic acid ethyl ester

FINAL.

In accordance with M.P.E.P. §821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Claims 51 and 54-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions. Applicant timely traversed the restriction (election) requirement in the reply filed on January 10, 2005.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The Information Disclosure Statements filed on November 4, 2003 and May 6, 2004 have been considered by the Examiner.

Claim Rejections – 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 22, "Thecompound" should be changed to "The compound". In claim 39, "characterized" is misspelled. Also in claim 39, "characterized by" should be changed to "of".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 16-20, 22-26, 29-35, 39-44, 46, 47, 50, 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hulin {WO 91/19702}, taken alone, or in combination with the teachings of Brooks et al. {WO 02/16331}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim oxazole compounds. Hulin teaches oxazole compounds that are structurally similar to the instant claimed

compounds. See in Hulin (pages 6-7), for example, Formula (II) wherein Z is alkyl; Z¹ is alkyl; X is O; Y is N; m is 2; W is O; ----- represents no bond; X¹ is O; R is alkyl; and Y¹ is hydroxy. Also note Example 13 on page 39.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the compounds of Hulin and the instant claimed compounds is that of a hydrogen (in the teaching of Hulin) versus a homolog such as a methyl group (instant R³-R⁶ variables, note proviso) attached to the phenyl ring in instant formula (I).

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

To those skilled in chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. In re Henze, 85 USPQ 261 (1950). Additionally, it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable

modification absent unexpected or unobvious results. *In re Wood*, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and *In re Lohr*, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., a hypoglycemic agent).

Alternatively, Brooks et al. teach the interchangeability of hydrogen versus an alkyl group on said phenyl ring in hypoglycemic agents. See in Brooks et al. the definition of the Y variable on page 4 (e.g., unsubstituted or substituted phenylene); the possible substituents on the phenylene found on page 6, lines 28-30; the use on page 5; and especially Example 14 on page 83.

The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare homologs of the compounds taught in Hulin, or alternatively, especially in view of the teachings of Brooks et al., to arrive at the instant claimed compounds with the expectation of obtaining compounds which could be used as hypoglycemic agents. The instant claimed invention would have been

suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

The elected species of Example 47 is not allowable over the art of record.

Allowable Subject Matter

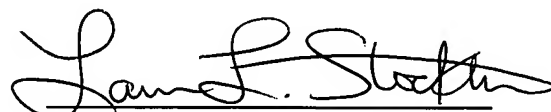
Claims 13-15, 21, 27, 28, 36-38, 48 and 49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from

either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

February 22, 2005